IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

UNITED STATES OF AMERICA ex rel. KEVIN GRAY,	)	
Plaintiff-Relator,	)	Civil Action No: 3:15-cv-127-MPM-JMV
v.	)	
MITIAS ORTHOPAEDICS, PLLC, and HANNA M. MITIAS, M.D.,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF RESPONSE IN OPPOSITION TO DEFENDANTS' JOINT MOTION TO DISMISS

Defendants Mitias Orthopaedics, PLLC, and Hanna M. Mitias, M.D., (collectively "Defendants" or "Mitias") jointly move to dismiss the Government's Complaint in Intervention (Dkt. 37 or "Complaint") pursuant to Fed. R. Civ. P. 12(b)(6). Mitias violated the federal False Claims Act ("FCA") by knowingly submitting false claims to federal healthcare programs (collectively, "Medicare") for reimbursement for services and devices that were not actually provided, were not medically reasonable or necessary, and/or were not covered by Medicare. Because the Government has adequately pled all the elements of an FCA violation, the Court should deny Defendants' Motion.

I. INTRODUCTION

The Government's case in chief is simple: Defendants submitted claims to Medicare for non-covered, non-FDA-approved, products under billing codes for covered, FDA-approved, products. Healthcare providers may not bill Medicare for snake oil. The False Claims Act was enacted during the Civil War to address exactly this type of fraud. *See U.S. ex rel. Newsham v.*

Lockheed Missiles & Space Co., 722 F. Supp. 607, 609 (N.D. Cal. 1989) ("For sugar it [the government] often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys….").

As treatment for osteoarthritis of the knee, Mitias injected patients with a viscosupplementation agent ("VA") containing hyaluronan[1] that was unlawfully manufactured and sold by a compound pharmacy. Dkt. 37, *passim*. Mitias billed Medicare for these injections (for both the service and the device) under J-codes for brand-name VAs such as Synvisc or Euflexxa. *Id.* Mitias gave no indication that it had injected the patients with, and was billing Medicare for, substances that were not the brand-name VA but rather a non-approved device.[2] *Id.* As a result of these claims, Medicare reimbursed Mitias for the brand-name devices. *Id.*

These claims were false for four primary reasons. First, the claims were factually false because Mitias submitted claims for a different substance than was actually injected. Second, the claims were legally false because Mitias submitted claims for a substance that was not FDA-approved and that did not fall under a statutory exception for a non-FDA-approved product, and so was not covered by Medicare. Third, the claims were legally false because Mitias cannot provide documentation to support the medical necessity or reasonableness of the claims. And

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[1] A viscosupplementation agent is a device injected into the knee joint to relieve pain associated with osteoarthritis. Hyaluronan, also known as hyaluronic acid, is a chemical compound that is an ingredient in the VAs. These terms are *not* interchangeable, as Defendants suggest. *See* Dkt. 43 at 1.

[2] Defendants' use of the terms "generic" and "compound" is misleading, because unlike with drugs, there really is no such thing as a generic device or a compound device. Individual devices from a particular manufacturer are approved by the FDA for specific uses. A compound drug is a mixture of existing drugs, for which each individual component is billed to Medicare under their respective codes; combining two approved devices simply results in an unapproved, adulterated device. Similarly, generic drugs still go through an FDA-approval process. A generic device, in this context, is an unapproved imitation. Accordingly, the Government uses the term "non-approved."

fourth, the claims were factually false because they were submitted under a qualified provider when injections were performed by non-qualified technicians.

The Government further contends that Mitias knowingly made false records material to the aforementioned false claims by documenting injections of brand-name devices rather than injections of the non-approved VAs, in violation of 31 U.S.C. § 3729(a)(1)(B).[3]

At all times relevant to the Complaint, Mitias had knowledge, as that term is defined by the federal False Claims Act, that the claims it submitted for reimbursement were false and material to the Government's decision to pay, and that the false records were material to the false claims. Accordingly, the Court should deny Defendants' motion.[4]

II. LEGAL STANDARDS

A. Fed. R. Civ. P. 12(b)(6)

"A district court should dismiss for failure to state a claim only if 'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *U.S. ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 375 (5th Cir. 2004)

[3] The Complaint mistakenly cites to the pre-2009 amendment version of the False Claims Act, 31 U.S.C. § 3729(a)(2). Dkt. 37, ¶ 85. The version of the statute in effect at all relevant times—31 U.S.C. § 3729(a)(1)(B)—requires only that a record be "material" to a false claim and does not require that the record was made to get a false claim paid. *See U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 717 n.39 (N.D. Tex. 2011).

[4] The Government also alleges a count of unjust enrichment. Dkt. 37, Count IV. Mitias addresses this claim with only a single unsupported contention that materiality is an element of unjust enrichment. Dkt. 43 at 2. The Fifth Circuit has previously declined to apply the False Claims Act's materiality requirement to claims of unjust enrichment. *See XL Specialty Ins. Co. v. Bollinger Shipyards, Inc.*, 800 F.3d 178, 184 (5th Cir. 2015); *c.f. Golden Triangle Vein Ctr. v. Total Body Contouring, Inc.*, 2017 U.S. Dist. LEXIS 42281, at *9 (N.D. Miss. Mar. 23, 2017) (applying element of materiality to fraudulent misrepresentation claim but not unjust enrichment claim). Regardless, as explained *infra*, the Government has adequately pled materiality.

(quoting *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)). "The complaint must be liberally construed in favor of the plaintiff, and all well-pleaded facts accepted as true." *Id.*[5] "Even if it seems 'almost a certainty to the court that the facts alleged cannot be proved to support the legal claim,' the claim may not be dismissed so long as the complaint states a claim." *Id.* at 376 (quoting *Boudeloche v. Grow Chem. Coatings Corp*., 728 F.2d 759, 762 (5th Cir. 1984)).

B. False Claims Act – 31 U.S.C. § 3729

A violation of the False Claims Act "occurs when '(1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter;[6] (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim).'" *U.S. v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 260 (5th Cir. 2014) (quoting *U.S. ex rel. Longhi v. Lithium Power Techs., Inc*., 575 F.3d 458, 467 (5th Cir. 2009)); *see also* 31 U.S.C. § 3729(a)(1)(A), (B). Allegations of falsity and materiality must meet the particularity requirements of Rule 9(b); scienter "need only be pled plausibly pursuant to Rule 8." *Id.*

Claims violating the FCA can be either factually false or legally false. "'Factually false' claims involve 'an incorrect description of goods or services or a request for reimbursement for goods or services never provided.' Alternatively, 'legally false' claims arise when a party that submits claims to the government affirmatively certifies compliance with a statute or regulation and the certification is a material condition to receiving a government benefit." *U.S. ex rel.*

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[5] Much of Mitias's brief is more appropriate for summary judgment arguments, but Dkt. 43, Section E in particular steps well over the line of what is proper for a motion to dismiss, denying the factual allegations raised herein and making unsupportable contentions that evidence of absence equates to absence of evidence. Dkt. 43 at 16-19. The Government is not required to prove its case at the pleading stage. *Grubbs*, 565 F.3d at 189. The Court should give no credence to these arguments.

[6] The legal standard for scienter under the False Claims Act is discussed in Section III(E), *infra*.

Waldmann v. Fulp, 259 F. Supp. 3d 579, 590 (S.D. Tex. 2016) (quoting *U.S. ex rel. Bennett v. Medtronic*, 747 F.Supp.2d 745, 765-66 (S.D. Tex. 2010)); *see also Universal Health Servs. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016) (certifications can be either "express" or "implied").

C. Materiality under the False Claims Act

In *Universal Health Servs. v. U.S. ex rel. Escobar*, the Supreme Court explained that implied certification supports FCA liability where a party makes specific representations about the services provided but fails to disclose non-compliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths. 136 S. Ct. 1989, 2001 (2016).[7] A misrepresentation is "material" if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at 1996. Thus, a false claim or statement is material if "either (1) a reasonable person would likely attach importance to it or (2) the defendant knew or should have known that the government would attach importance to it." *Id*. at 2002-03.

The Fifth Circuit has described the *Escobar* inquiry as "holistic." *U.S. ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 161 (5th Cir. 2019). Accordingly, it considers, for example, whether the alleged violations were labeled as conditions of payment; whether the Government routinely enforces these provisions, such as through legal or enforcement actions; and whether the noncompliance was "minor or insubstantial." *Id.* at 161-163. No one factor is dispositive. *Id.*

[7] There is a split of authority as to whether *Escobar* altered the materiality analysis for express certifications. *U.S. ex rel. Hussain v. CDM Smith, Inc.*, 2017 U.S. Dist. LEXIS 159538, at *18 n.3 (S.D.N.Y. Sep. 27, 2017) versus what on the other side?

D. Local Coverage Determinations

LCD L32237, and subsequently L35427 (collectively, "L32237" or "the LCD"),[8] establish coverage indications, limitations, and medical necessity for the use of hyaluronan acid therapies for osteoarthritis of the knee. Dkt. 37, ¶ 78 fn.6. It explains that "[a]ll providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for hyaluronate polymers services and must properly submit only valid claims for them." Two of the first three sentences of the LCD's Coverage Guidance further address the materiality of the violations discussed there: "It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered…. Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits."

Medicare Administrative Contractors ("MAC") such as Novitas can make their own determinations as to "which items are reasonable and necessary for purposes of coverage under the statute." *U.S. ex rel. Colquitt v. Abbott Labs.*, 2016 U.S. Dist. LEXIS 1556, at *11 (N.D. Tex. Jan. 7, 2016). They may then issue LCDs "that address the reimbursement eligibility of certain procedures," which are "binding [] in the local areas for which the particular contractor has authority." *Id.* (citing 42 U.S.C. § 1395ff(f)(2)(B)).[9] Various courts, including in *Colquitt*, have held that noncompliance with LCDs may give rise to liability under the False Claims Act. *See U.S. ex rel. Alt v. Anesthesia Servs. Assocs., PLLC*, 2019 U.S. Dist. LEXIS 223011, at *43 (M.D.

[8] Although the LCD was periodically updated, the relevant content remained the same. A copy of the original LCD is attached hereto as Exhibit A.

[9] Even if the Court declines to hold that L32237 is binding, the LCD still establishes scienter and materiality by putting Mitias on notice of what the MAC, on behalf of CMS, considers to be covered and what conditions are required to be met for payment.

Tenn. Dec. 31, 2019) (listing cases).

Mitias contends that *Azar v. Allina Health Services,* 139 S. Ct. 1804 (2019), bars the Government from basing its case on an LCD. Dkt. 43 at 7 and 16. *Allina* addressed whether CMS could administratively "pull a surprise switcheroo," by unilaterally and retroactively changing how it calculated Medicare Part A reimbursements without following notice-and-comment rule-making procedures. 139 S. Ct. at 1810. But nothing in *Allina* addresses the issues in this case: whether a service is "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A), the statutory authority afforded to MACs to make those determinations under 42 U.S.C. § 1395ff(f)(2)(B), or the application of LCDs to False Claims Act cases. For these same reasons, the court in *Alt* declined to apply so broad a reading of *Allina*:

> *Allina* did not concern LCDs and certainly did not establish that **all** LCDs set forth substantive legal standards, nor did it address the question of whether a false certification of compliance with an LCD may form the basis of a claim under the FCA. Moreover, neither party here has actually briefed the question of whether the particular LCDs at issue should be considered to establish substantive legal standards, nor have the parties addressed the question of whether *Allina* has any application at all in the context of a case asserting FCA claims, as opposed to a case specifically contesting the denial of Medicare claims for reimbursement. At this juncture, the court does not read *Allina* to support dismissal of any claims asserted in this case.

2019 U.S. Dist. LEXIS 223011, at *45-46 (M.D. Tenn. Dec. 31, 2019).

Polansky v. Exec. Health Res., Inc., did apply *Allina* to a False Claims Act case, but only after a painstaking explanation that the FCA claims were premised entirely on guidance from CMS manuals. 2019 U.S. Dist. LEXIS 192332 (E.D. Pa. Nov. 5, 2019). Unlike LCDs, there is no statutory authority for CMS manuals, and so they are not binding authority. *U.S. ex rel. St. John LaCorte v. SmithKline Beecham Clinical Labs., Inc*., 1999 U.S. Dist. LEXIS 13036, at *31 (E.D. La. Aug. 19, 1999). Conversely, LCD L32237 interprets the proper application of pre-existing statutory authority such as 42 U.S.C. § 1395y(a)(1)(A) to address what and how VA injections

are covered by Medicare. Other courts have already considered, and rejected, Mitias's argument regarding local or national coverage determinations that "'create no new law' but simply 'interpret the statutory language 'reasonable and necessary' as applied to a particular medical service or method of treatment.'" *U.S. ex rel. Lynch v. Univ. of Cincinnati Med. Ctr., LLC*, 2020 U.S. Dist. LEXIS 48214, at *45-54 (S.D. Ohio Mar. 20, 2020) (citing *Friedrich v. Sec'y of Health and Human Servs*., 894 F.2d 829, 837-38 (6th Cir. 1990)); *see also Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 n.6 (5th Cir. 2001) ("Agencies need not provide notice and comment for every meaningful policy decision. Interpretations of ambiguous or unclear regulations by agencies may be exempt from the APA's notice and comment requirement."). Thus, the only case the Government is aware of having applied *Allina* in the context of a False Claims Act case is easily reconcilable.

Mitias proposes that *Allina* supports sweeping propositions such as that "[a] policy that affects a provider's right to payment is substantive," but this not so. *Allina* expressly declined to issue *any* such bright-line rules, instead "follow[ing] the well-worn path of declining 'to issue a sweeping ruling when a narrow one will do.'" 139 S. Ct. at 1814 (limiting holding to "whether the Medicare Act borrows the APA's interpretive-rule exception"); *see also Polansky*, 2019 U.S. Dist. LEXIS 192332, at *39 (only the D.C. Circuit has adopted a definition of "substantive legal standard," which the Supreme Court declined to adopt). And Mitias's argument that every "policy that affects a provider's right to payment is substantive" (Dkt. 43 at 7) cannot be correct. 42 U.S.C. § 1395hh(2) addresses rules or statements of policy that (a) "establishes or changes a substantive legal standard…" (b) "governing the scope of benefits, the payment for services," etc. If all policies governing payment are substantive legal standards, then the "substantive legal standard" language is superfluous, and the Supreme Court's analysis in *Allina* would have been

unnecessary.[10] Mitias has failed to properly brief the relevant issues, and so like the court in *Alt*, this Court should decline to consider the argument.

But even were Mitias correct, which it is not, *Allina* does not moot the relevance of the LCD with regards to materiality and scienter. Novitas issued guidance as to how to bill for VAs, and in doing so put Mitias on notice of the violations alleged herein and that they were material. LCD L32237 explains that "[a]ll providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for hyaluronate polymers services and must properly submit only valid claims for them." The LCD's Coverage Guidance similarly warns providers of materiality: "It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered…. Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits."

III. ARGUMENT

A. Mitias Knowingly Submitted False Claims for Non-Covered Devices Under Codes for Covered Devices

When a provider seeks reimbursement from Medicare, it submits a claim indicating the billing codes for the services, drugs, or devices for which it seeks reimbursement. These codes and instructions as to how and when to bill to these codes are published in the Current Procedural Terminology Coding Manual and Health Care Financing Administration Common

[10] LCD L32237 in particular does not establish or change any substantive legal standards. It does not establish the rule that Mitias can only bill for what services it actually provides; or that Medicare will not reimburse for these non-FDA-approved devices; or that services must be medically reasonable or necessary, with supporting documentation; or that services must be provided by qualified individuals. These are longstanding, binding, commonsense rules, and the mere inclusion of them in this particular LCD does not render them invalid.

Procedure Coding System (HCPCS), adopted by the federal Government pursuant to 45 C.F.R. § 162.1002. Accordingly, claims submitted contrary to the requirements of these manuals, such as by billing for a service or item that is different from what was actually provided, are false.

1. *The Claims were Factually False because they Misrepresented what was Provided.*

During the relevant time periods, only eight intra-articular hyaluronic acid derivative devices had been approved by the FDA for the treatment of osteoarthritis in the knee, for which there existed six specific billing J-codes. Dkt. 37, ¶¶ 30-36. As different VAs may cost more or less than the others, each J-code reimbursed a different amount to reflect the cost of that particular VA. *Id.*, ¶¶ 25-27.

By their plain language, the billing codes do not allow for the submission of any devices other than those listed.[11] Using J7324 as an example, it permits billing of "Hyaluronan or derivative, Orthovisc…." The preceding clause, "hyaluronan or derivative," is a descriptor of the brand-name product, Orthovisc, an FDA-approved product that "is comprised of highly purified sodium hyaluronate (NaHA) in physiologic saline."[12] A "derivative" is a "chemical substance related structurally to another substance."[13] Sodium hyaluronate is a derivative of hyaluronan a/k/a hyaluronic acid. Accordingly, it is appropriate to bill Orthovisc, which is "hyaluronan or derivative, under J7324. Each FDA-approved VA is different, with different solutions and

[11] It is unclear whether Defendants are arguing that the claims are not false because the billing codes permits them to bill non-approved VAs, or if they are merely suggesting they had an "honest belief" in their interpretation. *See* Dkt. 43 at 13-14 (couching arguments in terms of materiality and scienter). "The issue of falsity goes to whether a claim is objectively correct, not to whether the defendant or anyone else, subjectively believes it is correct," and so Mitias's "belief" is irrelevant to this analysis. *U.S. ex rel. Wright v. Agip*, 2007 U.S. Dist. LEXIS 103663, at *23 (E.D. Tex. June 28, 2007) (citing *U.S. ex rel. Oliver v. Parsons Co*., 195 F.3d 457, 463 (9th Cir. 1999)); *see also* Section III(E), *infra*.

[12] https://www.anikatherapeutics.com/products/orthobiologics/orthovisc/ (last visited March 24, 2020).

[13] https://www.merriam-webster.com/dictionary/derivative (last visited March 24, 2020).

molecular weights, but they share the characteristic that hyaluronan or a derivative are their active ingredient. Thus they are classified by this descriptor, of "hyaluronan or derivative."

Mitias purchased hyaluronic acid devices that were not any of the aforementioned approved devices from a compound pharmacy. *See, e.g., id.*, ¶¶ 46, 59, 73. It injected its patients with those non-approved devices and billed Medicare for them using the device-specific J-codes. *Id.*, ¶¶ 58-62. Every claim submitted with one of those J-codes was factually false because the inclusion of that particular J-code on the claim indicated that the associated device had been used. *C.f. U.S. ex rel. Patel v. Catholic Health Initiatives*, 312 F. Supp. 3d 584, 603 (S.D. Tex. 2018) (citing *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 899-902 (9th Cir. 2017)) ("seeking reimbursement for approved drugs, when 'unapproved knock-offs' were actually used, is also an instance of factual falsity").

Mitias suggests the codes permit it to bill for any viscosupplementation agent, regardless of FDA-approval, so long as they contain hyaluronan or a hyaluronan derivative. This reading is contrary to the plain language and context of the codes.

"Ambiguous provisions are interpreted according to their plain language and all terms are given meaning. A clause is ambiguous only if it can be reasonably interpreted in multiple ways, but mere interested disagreement between the parties is not ambiguity." *U.S. ex rel. Sorensen v. Outreach Diagnostic Clinic LLP*, 2020 U.S. Dist. LEXIS 46912, at *5 (S.D. Tex. Mar. 16, 2020) (citing *Reliant Energy Serv. Inc., v. Enron Canada Corp.*, 349 F.3d 816, 822 (5th Cir. 2003)).

In *Sorensen*, the court applied a common sense reading of the billing codes to reject the defendant's argument of ambiguity. Defendant Outreach was alleged to have violated the FCA by billing for tonometry under the code for tonography, "a procedure related to—yet distinct from—tonometry." *Id.* at *3. The Government contended that CPT Code 92120—"Tonography

with interpretation and report, recording indentation tonometer method or perlimbal suction method"—refers to one procedure (tonography) that can be performed in one of two ways. *Id.* at *5-6. Defendant Outreach claimed that the code could be interpreted as covering three different procedures—a) tonography with interpretation and report, b) recording indentation tonometer method, or c) perlimbal suction method—because "the comma after the word 'report' shows that the code refers to a series of services." *Id.* at *6.

The court not only rejected Outreach's interpretation, but it found there to be no ambiguity in the billing code. Outreach's interpretation was "inconsistent with the language of the rules and prevailing medical practice." *Id.* at *6, 12. Applying a "plain language reading of the code," the Court noted that "other CPT codes use an Oxford comma or a semicolon when listing separate categories, while Outreach's construction of the code does not." *Id.* at *6-7. It further noted that Outreach's interpretation required "inconsistent phraseology." *Id.* at *6. The court thus found summary judgment to be appropriate where the provider "create[d] ambiguity out of clarity." *Id.* at *7.

Mitias's proposed interpretation of J7325 parallels Outreach's argument: that rather than being a descriptor, "Hyaluronan or derivative, Synvisc or Synvisc-One" is a list of four separate devices that can be billed under the J-code: a) hyaluronan, b) hyaluronan derivative, c) Synvisc, or d) Synvisc-One. This interpretation ignores the lack of an Oxford comma or semicolon.[14] Moreover, it requires inconsistent phraseology, as evinced by J7324: "Hyaluronan or derivative, Orthovisc." Were Mitias's interpretation correct, this J-code would necessarily read "Hyaluronan or derivative or Orthovisc."

[14] The correct phrasing to support billing as Mitias suggests would be "Hyaluronan, hyaluronan derivative, Synvisc, or Synvisc One."

Mitias's understanding further begs the question of why HCPCS would have multiple codes when all of the brand-name VAs include hyaluronan and thus could have been billed under one single code? It also ignores that while the VAs have always been regulated as devices (*see* Section III(A)(2), below), hyaluronan is not device, it is a chemical compound, an ingredient in the devices. Mitias proffers that the Court should ignore the entire universe of authority addressing VAs as devices and read these codes as each applying to one or two brand-name VAs, specifically, as well as any other non-approved device that contains hyaluronan, and even simply the chemical compound hyaluronan by itself.[15]

A far more natural and consistent reading, which is the correct reading, is that each code identifies a specific brand-name product, each of which is described as "hyaluronan or derivative," and it is *Mitias's* proposed understanding that renders part of the description—the brand-name drug(s)—superfluous. The Court should not permit Mitias to "create ambiguity out of clarity" and so should hold that billing for the unapproved VAs under these J-codes is false.

2. The Claims were Legally False Because Medicare Does Not Cover Non-Approved VAs.

Federal statute expressly prohibits payments under Medicare Part B for "expenses incurred for items or services" that "are not reasonable and necessary for the diagnosis or

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[15] This same definition and application are provided in the May 30, 2012 letter (*see* Dkt. 37, ¶¶ 68-69), attached hereto as Exhibit B: "This letter is in response to your request for the definition of derivative as it relates to HCPCs codes J7321-J7325. A derivative is a chemical substance that is related structurally to another chemical substance. Hyalgan, Supartz, Euflexxa, Orthovisc, Synvisc or Synvisc-One are all derivatives of Hyaluronon [sic]. Therefore, if Hyalgan or Supartz is administered it would be appropriate to report HCPCS code J7321…"

[15] It is further worth noting that although the "long description" of the billing codes are listed in paragraphs 31-36 of the complaint, the relevant HCPCS manuals from those periods also contained "short descriptions" that removed any notion of ambiguity. For example, the short descriptions for J7321-J7325 were Hyalgan/supartz inj per dose; Euflexxa inj per dose; Orthovisc inj per dose; and simply "Synvisc or Synvisc-One," respectively.

treatment of illness or injury…"42 U.S.C. § 1395y(a)(1)(A). Additional federal statutes, regulations, and coverage determinations address what is medically reasonable and necessary and what is covered by Medicare. Under these statutes, regulations, and coverage determinations, the VAs used by Mitias are not covered by Medicare.

First, the Government must address Defendants' claim that VAs are not Class III devices. Dkt. 43 at 16. It is well-established, including under Fifth Circuit authority, that at all times relevant to this action, intra-articular hyaluronic acid products were classified and regulated as Class III devices. *See Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 241 (5th Cir. 2002) ("The Food and Drug Administration ('FDA') granted Biomatrix's pre-market approval application in August of 1997, and classified Synvisc as a 'Class III' device for purposes of the Medical Devices Act.").[16] This conclusion is consistent with 21 U.S.C. § 360c(a)(1)(C) and (f), which explain when a device is Class III (primarily that it fails to meet the requirements of Classes I or II).[17] *See also* 21 U.S.C. § 321(h) (defining "device"); Medicare Benefit Policy Manual Chapter

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[16] Mitias cites a notice from **2018** "announcing [the FDA's] intent to consider" reclassifying VAs for osteoarthritis, and that some VAs "may not meet the definition of a device" but that others may. Dkt. 43 at 17 (quoting 83 Fed. Reg. 64,844 (Dec. 18, 2018)). Whether the devices are ultimately reclassified or not is wholly irrelevant because VAs with hyaluronan "for this use has been regulated as a Class III device." 83 Fed. Reg. 64,844. *See also* Dkt. 37, ¶¶ 25, 37, 76 (contradicting Defendants' argument—Dkt. 43 at 12—that the inclusion of VAs in the HCPCS manual qualified them as "drugs"). Regardless, Medicare generally will not reimburse for drugs that are not FDA-approved or that are misbranded or adulterated. *Campie*, 862 F.3d at 897; *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701 (4th Cir. 2014). And were the VAs treated as drugs, the claims would still be false at least because Mitias requested reimbursement for brand-name products and not bulk ingredients. *See* Medicare Claims Processing Manual, Chapter 17, ¶ 20.1.2 (citing Section 303(c) of the Medicare Modernization Act of 2003 pricing) (until July 2015, drugs generally priced based on average sales price (ASP) methodology, but "[p]ricing for compounded drugs is performed by the local contractor").

[17] Devices that are "substantially equivalent" to another Class III device are also classified as Class III devices, but a device can only be deemed "substantially equivalent" by order of the Secretary of Health and Human Services. 21 U.S.C. § 360c(i)(1). In other words, even if the non-approved VAs were identical to the brand-name products, they still would have to go through a review process to be deemed Class III devices. *C.f.* 21 U.S.C.S. § 355 (discussing approval process for generic drugs).

14, § 10 (same). LCD L32237 also identifies the brand-name VAs as "[v]arious polymers hyaluronic acid [that] have been approved and marketed as implanted prosthetic devices."

Mitias next argues that the Government has inadequately pled its claims because Medicare does cover *some* non-FDA-approved devices, Dkt. 43 at 10. This argument is semantic at best, because none of the exceptions to this general principle applied to the VAs used by Mitias. Pursuant to the Medicare Benefit Policy Manual, Chapter 14, § 10, Coverage of Medical Devices:

> For dates of service on or after November 1, 1995, Medicare may cover certain FDA-approved and Institutional Review Board (IRB)-approved investigational devices and services incident to, provided the investigational device meets certain requirements, including:
>
> • The device or services associated with the use of a device were provided to the beneficiary within the start and end dates contained in the master file;
>
> • There are no regulations, national coverage policies, or manual instructions that would otherwise prohibit Medicare coverage.
>
> Devices that may be covered under Medicare include the following categories:
>
> • Devices approved by the FDA through the Pre-Market Approval (PMA) process;
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> • Devices cleared by the FDA through the 510(k) process;
>
> • FDA-approved Investigational Device Exemption (IDE) Category B devices;[18] and

[18] Mitias seizes upon inapposite language in 42 C.F.R. § 405.201(a)(1) that "FDA categorization of a device" is a "factor" in Medicare coverage decisions. Dkt. 43 at 10. This subpart is limited to devices under FDA-approved IDE; an IDE requires an "an FDA-approved IDE application that permits a device" to be used for a clinical study; and the "categorization" is of whether the device itself is experimental or not. Thus FDA categorization is a "factor" because IDE Category A (experimental) devices are not covered and IDE Category B (nonexperimental/investigational) devices *may* be covered. *See* 42 C.F.R. § 405(a)(2) and (b); *see also* 42 C.F.R. §§ 405.201 *et seq*.; 78 Fed. Reg. 74230, 74429-37 (Dec. 10, 2013).

• Hospital IRB-approved non-significant risk devices.

The non-approved VAs do not fall under any of these categories. *See also* LCD L32237 (limiting coverage to FDA-approved VAs, citing Chapter 14 as relevant authority).[19]

In 2003, CMS stated unequivocally that unless a device falls under one of the listed exceptions, it must be FDA-approved to be covered by Medicare:

> Both CMS and the FDA review scientific evidence, and may review the same evidence, to make purchasing and regulatory decisions, respectively. However, CMS and its contractors make coverage determinations and the FDA conducts premarket review of products under different statutory standards and different delegated authority (67 FR 66755, November 1, 2002). Whereas the FDA must determine that a product is safe and effective as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A) of the Act. CMS adopts FDA determinations of safety and effectiveness, and CMS evaluates whether or not the product is reasonable and necessary for the Medicare population. Although **an FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for Medicare coverage, except for Category B devices under an IDE clinical trial** (see 60 FR 48417, September 19, 1995), FDA approval/clearance alone does not generally entitle that device to coverage.

Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 FR 55634, 55636, 2003 WL 22213011 (Sept. 26, 2003). Courts have thus held that "FDA approval is required for CMS to consider Class III medical devices to be reasonable and necessary." *U.S. ex rel. Higgins v. Bos. Sci. Corp.*, 2017 U.S. Dist. LEXIS 138767, at *19-21 (D. Minn. Aug. 29, 2017) (citing 42 C.F.R. § 405.201(a)(1); 68 FR 55634-01; *Int'l Rehab. Scis. Inc.*

[19] 21 U.S.C. § 360c(a)(1)(C) requires that a Class III device "be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness." Pursuant to 21 U.S.C. § 351(f)(1)(B), any device classified as Class III that is not exempt that does *not* have an approved application for premarket approval, is "adulterated." Dkt. 37, ¶ 39, 75; *see also In re Grand Jury Subpoena*, 220 F.R.D. 130, 154 (D. Mass. 2004) (listing the "many ways a device can qualify as 'adulterated'"); 21 U.S.C. § 352 (misbranded devices).

v. Sebelius, 688 F.3d 994, 1002 (9th Cir. 2012) ("FDA clearance . . . is **necessary**, but not **sufficient**, for Medicare coverage."); *c.f. U.S. ex rel. Colquitt v. Abbott Labs.*, 2016 U.S. Dist. LEXIS 1556, at *13 (N.D. Tex. Jan. 7, 2016) (citing 68 Fed. Reg. 55634).[20]

L32237 further explains that for Medicare to "cover the cost of the injection and the injected hyaluronate polymer… [t]he prosthetic device [must be] approved by the Food and Drug Administration (FDA) for intra-articular injection." It also defines when a VA injection can be considered reasonable and necessary, including requiring that the service be "[s]afe and effective." *See* 68 FR 55634 ("CMS adopts FDA determinations of safety and effectiveness"); *see also* Dkt. 37, ¶¶ 56-57 (non-FDA-approved devices could, and allegedly did, cause harm to patients).

Because the devices were not FDA-approved and did not fall under an exception, they were not medically reasonable or necessary and thus not covered by Medicare. Dkt. 37, ¶ 39, 75. *See also* 21 U.S.C. § 360c(a)(1)(C) (Class III devices require PMA); 21 U.S.C. § 351(f)(1)(B) (Class III device that is not exempt and does not have PMA is "adulterated"); 21 U.S.C. § 352 (misbranded devices); *c.f.* Medicare Benefit Policy Manual, Chapter 15, § 50.4.1 (requiring CMS or FDA approval for a drug to be considered "safe and effective" and therefore covered); *Id.*, § 50.4.7 (adulterated or misbranded drugs, including those not approved by FDA for marketing, are not reasonable and necessary and thus not covered).

3. *The Violations Were Material Because They Caused Medicare to Pay Amounts it Otherwise Would Not Have Paid.*

The alleged violations are material because they influenced the payment of money.

[20] In *Colquitt*, summary judgment was denied because relator had not established "beyond peradventure" that an off-label **use** of an otherwise FDA-approved product was not covered. *Id.* at *13-14.

Nothing in *Escobar* requires the court to abandon common sense when considering the materiality of a violation. To the contrary, "both the facts of *Escobar* and the Court's analysis 'illustrate that materiality is essentially a matter of common sense rather than technical exegesis of statutes and regulations.'" *U.S. ex rel. Bonzani v. United Techs. Corp*., 2019 U.S. Dist. LEXIS 182401, at *19 (D. Conn. Oct. 22, 2019) (quoting *U.S. ex rel. Gelman v. Donovan*, 2017 U.S. Dist. LEXIS 156413, at *14 (E.D.N.Y. Sep. 25, 2017)).

What services and items are billed, and thus what services and items are paid for by Medicare, goes to the "very essence of the bargain." *Escobar*, 136 S. Ct. at 2003 n.5 (quoting *Junius Constr. Co. v. Cohen*, 257 N.Y. 393, 400 (1931)). The "false claims were not simply material to receiving Medicare payments, they were critical." *U.S. ex rel. Sorensen v. Outreach Diagnostic Clinic LLP*, 2020 U.S. Dist. LEXIS 46912, at *11 (S.D. Tex. Mar. 16, 2020). Because "a reasonable person" would attach importance to billing for one product while failing to disclose that a cheaper, non-approved product was actually used, the violations were material.

There are other factors supporting a finding of materiality. Pursuant to 42 U.S.C. § 1395y(a)(1)(A) and other federal healthcare analogues, "no payment may be made… for any expenses incurred for items or services which… are not reasonable and necessary for the diagnosis or treatment of illness or injury…." *See also* Dkt. 37, ¶ 78; *Escobar*, 136 S. Ct. at 2003 (Government decision to expressly identify a provision as condition of payment is relevant factor). Furthermore, the Government has a long history of bringing, intervening, and prosecuting FCA cases where providers billed for services that were not provided, and the Government has even specifically prosecuted and intervened in False Claims Act cases against providers who used and billed for adulterated VAs. Dkt. 37 at 9 (*Estey* settlement); Dkt. 8, *United States v. Merriam Medical Management, Inc.*, Case No. 17-mj-8183-JPO (D. Kan. Sept.

27, 2018) (guilty plea); *see also Escobar*, 136 S. Ct. at 2003 (history of Government refusing to pay claims based on noncompliance with requirements is a factor).

A finding of materiality is warranted even under Defendants' flawed theory that it could have billed under a different code. Dkt. 43 at 14-15. Damages are not an element of a False Claims Act violation. *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir. 2009). What makes the violation material is that by falsely billing under *that* code, Mitias tricked the Government into paying him under *that* code; even if another code existed (unbeknownst to Mitias at the time it attempted the fraud), it would still at least be subject to civil penalties. *Id.* ("Put plainly, the statute is remedial and exposes even unsuccessful false claims to liability.").

Moreover, that code, if it existed, would not have reimbursed for the same amounts, and so the violations would still be material.[21] *See* Dkt. 37, ¶¶ 25-26. Reimbursement for each of the relevant J-codes were determined by a methodology set by statute for "single source drugs," which is based on the Average Sales Price ("ASP") of that particular drug. *See* 42 U.S.C. § 1395w-3a(b)(1)(B). If Medicare intended to cover additional devices under these same codes, it would have had to apply a different formula, for "multiple source drugs," so as to capture their

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[21] Defendants' argument that the devices could have been billed under J3490 is a red herring, if not an admission of liability. What Mitias has described amounts to a run-of-the-mill False Claims Act violation referred to as "upcoding": "billing Medicare or Medicaid for services under a code that is more expensive than the services the patient actually needed or was provided." *U.S. ex rel. Walker v. Corp. Mgmt.*, 2012 U.S. Dist. LEXIS 152618, at *6 (S.D. Miss. Oct. 24, 2012). In other words, even if Defendants **could** have billed the non-approved VAs under J3490, which the Government does not concede, they did **not** bill under J3490, and so the claims they submitted would still be false. By submitting the claims under the brand-name J-codes, Mitias avoided a determination of coverage and reimbursement rates that would have occurred under J3490, making the violation material. And even if the MAC *had* agreed to coverage (which it would not have), the payments under J3490 would have been much lower because they would have been based on the cost of the bulk hyaluronan, not the ASP of the brand-name product. Mitias has admitted as much, telling the relator that it chose to use non-approved VAs because the more expensive brand-name VAs cut into its profits. Dkt. 37, ¶¶ 64-71.

ASPs in the reimbursement methodology. *See* 42 U.S.C. § 1395w-3a(b)(1)(A).

As is evident across the fee schedules for all healthcare payors and in millions of drugstores, even if the non-approved VAs were covered (which they are not), a reasonable person would not pay brand-name prices for "generic" devices. Thus by misleading the Government as to what product it actually used, Mitias at the very least received a windfall to which it was not entitled.[22] Because use of the wrong code caused Medicare to pay money it otherwise would not have, these violations are material.

B. Mitias Failed to Maintain Adequate Documentation in Support of Medical Necessity and Reasonableness

Medicare operates under an "honor system," reimbursing providers on their word that claims are true and correct and do not violate federal law or program regulations. *See U.S. v. Bonham*, 1999 U.S. App. LEXIS 40207, at *5 (5th Cir. June 22, 1999) (Medicare relies "heavily, if not solely, on the representations the physician has made on the HCFA 1500 form"). Because "the government as insurer depends upon the honesty" of the provider, it "is easily taken advantage of if the [provider] is not honest." *U.S. v. Andradi*, 309 F. App'x 891, 894 (5th Cir. 2009) (quoting *U.S. v. Rutgard*, 116 F.3d 1270, 1293 (9th Cir. 1997)).

Instead of requiring providers to prove that each and every claim is legitimate (an impossible feat), Medicare periodically audits them and recoups payments for services when a provider cannot establish through supporting documentation that services were medically reasonable or necessary. *See Garcia v. Sebelius*, 2011 U.S. Dist. LEXIS 129662, at *20 (C.D. Cal. Nov. 8, 2011) (Medicare regulations put burden on provider to "provide sufficient evidence

[22] Moreover, Mitias's patients were also defrauded because they were billed for 20% of the calculated amounts. Dkt. 37, ¶ 27.

to establish the medical reasonableness and necessity of the services billed to Medicare") (citing 42 U.S.C. § 1395l(e)); *see also* LCD L32237 ("Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.").

For this reason, all Government Health Care Programs require that adequate documentation exist in the medical records. *See, e.g.*, 42 U.S.C. § 1395l(e) (Medicare: condition of payment that adequate documentation exists in the medical records); 42 U.S.C. § 1396a(a)(27) (Medicaid); *Rutgard*, 116 F.3d at 1287 (citing 42 U.S.C. § 1320c-5(a)(3)); 32 C.F.R. § 199.6(a)(5) (TRICARE services and supplies must "meet[] professionally recognized standards of health care [and be] supported by adequate medical documentation . . . to evidence the medical necessity and quality of services furnished…"); *c.f. Garcia v. United States*, 697 F. Supp. 1570, 1573-74 (D. Colo. 1988) (professional medical standards say part of duty of care owed to a patient by the provider is proper record keeping). Each HCFA-1500 claim form thus includes an express certification mirroring the language of 42 U.S.C. § 1395l(e), that, *inter alia*, "I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision."

LCD L32237 also requires providers to keep medical records supporting injections of VAs. Under Coverage Guidance, it states "[t]he appropriate records documenting the improvement must be maintained in the medical record and made available to Medicare upon request." The LCD also details what constitutes those "Documentation Requirements," including maintenance of the patient's medical record and support for use of the diagnosis code, as well as requiring "[t]he submitted CPT/HCPCS code must describe the service performed" and "[t]he medical record documentation must support the medical necessity of the services as directed in

this policy."

Every claim submitted by Mitias for VA injections included a false express certification that it had medical records to support the services being billed and a false implied certification that the claim abided by the requirements of LCD L32237. Medicare regulations establish record-keeping requirement as a condition of payment, and CMS routinely recoups payments when providers fail to keep records supporting the medical necessity and reasonableness of a service. Moreover, Mitias was aware that this requirement was material, as not only is it common knowledge and standard practice in the medical field that all services must be supported by the patients' records, but Mitias prepared false records to support its false claims. *See* Section III(C), below. Accordingly, failure to keep adequate records supporting the provision of VA injections renders those claims false and constitutes a material violation of the False Claims Act.

C. Mitias Knowingly Made False Records to Support Its False Claims

Even though Mitias never purchased any of brand-name VAs (Dkt. 37, ¶¶ 39, 46-78), it documented the use of brand-name devices in its patients (*id.*, ¶ 78) and told patients it was using brand-name VAs (*id.*, ¶ 58). These constitute false records and statements in violation of the False Claims Act.

For example, for Patient C in paragraph 78, Mitias submitted a false claim to Medicare for Orthovisc and documented "Orthovisc 30mg/2ml, Lot# 20151105@45," when it did not actually inject Orthovisc into Patient C. *Id.* Similarly, for Patient D, Mitias submitted a false claim to Medicare for Synvisc-One and documented an injection of Synvisc-One, when it did not actually inject Synvisc-One into Patient D.

As explained in Section III(B), above, these false records are material to Mitias's claims for payment for these injections. Accordingly, the Government is entitled to damages and civil penalties for each false statement or record material to a claim that Mitias injected a patient with

a brand-name VA.

D. Mitias Submitted False Claims under Dr. Mitias's NPI for Services Provided by Unqualified Technicians

L32237 states that for VA injections to be medically reasonable and necessary, they must be "[o]rdered and furnished by qualified personnel." Thus claims submitted to Medicare for services and devices related to VA injections performed by radiology technicians, but billed under Dr. Mitias, are false. *See* Dkt. 37, ¶¶ 51-52.

Under the incident to provisions, Medicare Part B will pay for services provided by "auxiliary personnel" incident to the services of a physician. *See* C.F.R. § 410.26. For example, if a supervising physician orders a flu shot, a registered nurse can perform the flu shot and the supervising physician can bill for that service. But that does not mean that just anyone employed by the physician can perform just any service; the service must be within the scope of the employee's practice:

> Auxiliary personnel means any individual who is acting under the supervision of a physician (or other practitioner)… **and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished**.

42 C.F.R. § 410.26(a)(1) (emphasis added); *see also* § 410.26(b)(6), (b)(7) (services must be furnished in accordance with applicable State law).

The radiologic technologists employed by Mitias were not licensed or qualified to perform VA injections. Under Miss. Code § 41-58-1(g):

> "Radiologic technologist" means a person other than a licensed practitioner who has passed a national certification examination recognized by the department such as the American Registry of Radiologic Technologists examination or its equivalent, who applies x-radiation or ionizing radiation to any part of the human body for diagnostic purposes and includes the administration of parenteral and enteral contrast media and administration of other medications or procedures incidental to radiologic examinations.

And under the Regulations Governing Registration of Medical Radiation Technologists, Title 15,

Part 19, Subpart 60, Rule 7.3.1:

> "Radiologic technologist registration" means the registration issued by the Department which permits a person to apply x-radiation or ionizing radiation to any part of the human body for diagnostic purposes, and includes the administration of parenteral and enteral contrast media and administration of other medications or procedures incidental to radiologic examinations.

That is the scope of practice for a licensed and certified radiologic technician, as defined by the State of Mississippi: to perform x-rays and administer contrast or medications incidental to radiologic examinations. There is nothing in the scope of their practice, as defined by the state, that allows a radiologic technician to perform dangerous procedures such as VA injections. They are technicians, not medical practitioners, and they are not authorized to engage in the practice of medicine. Accordingly, claims for injection services provided by the radiologic technicians, including the VAs injected, are false.

That services be performed by qualified providers was the very issue considered in *Escobar*. Applying the "holistic approach to determining materiality laid out by the Supreme Court," the First Circuit had "little difficulty" concluding that the complaint sufficiently alleged materiality because, in part, the state requirements of "adequate training and professional credentials" "go to the 'very essence of the bargain.'" *U.S. ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 110-111 (1st Cir. 2016); *see also U.S. ex rel. Waldmann v. Fulp*, 259 F. Supp. 3d 579, 585 (S.D. Tex. 2016) (state licensing laws are "some of Medicare's most basic requirements"; violations are material under *Escobar*).

This Court should find the same, that it is a material violation of the False Claims Act to allow unqualified employees to perform medical procedures on patients.

E. Mitias had Knowledge that the Claims were False and Material

"The False Claims Act defines the terms 'knowing' and 'knowingly' as a person that 'has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the

information; or acts in reckless disregard of the truth or falsity of the information.'" *U.S. ex rel. Jamison v. McKesson Corp.*, 2009 U.S. Dist. LEXIS 89807, at *35 (N.D. Miss. Sep. 29, 2009) (quoting 31 U.S.C. § 3729(b)). Knowledge under the FCA "require[s] no proof of specific intent to defraud." *Id.*

Healthcare providers "must turn square corners when they deal with the Government," which includes "a duty to familiarize itself with the legal requirements for cost reimbursement." *Heckler v. Cmty. Health Servs.*, 467 U.S. 51, 63, 104 S. Ct. 2218, 2225 (1984) (quoting *Rock Island, A. & L. R. Co. v. United States*, 254 U.S. 141, 143 (1920)). "Deliberate ignorance," therefore, contemplates "'constructive knowledge' or 'what has become known as the ostrich type situation where an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted.'" *U.S. ex rel. Longhi v. Lithium Power Techs., Inc.*, 513 F. Supp. 2d 866, 875-76 (S.D. Tex. 2007) (citing S. Rep. 99-345, at 20, U.S.C.C.A.N. 5266, 5285). Reckless disregard "has been described as 'gross negligence plus.'" *Id.* at 876 (quoting *U.S. v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997)); *see also U.S. v. Stevens*, 605 F. Supp. 2d 863, 867 (W.D. Ky. 2008) ("a physician demonstrates 'reckless disregard' when he fails to take reasonable steps to ensure that his clinic's claims for governmental reimbursement are accurate").[23]

Scienter "need only be pled plausibly pursuant to Rule 8." *Bollinger*, 775 F.3d at 260.

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[23] Effective January 22, 2015, Ageless Men's Health—a company co-owned by Dr. Hanna Mitias—settled allegations of billing for medically unnecessary services raised under the False Claims Act for $1.6 million and entered into a Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services. *See U.S. ex rel. Booth v. Ageless Men's Health*, 13-2490-SHL (W.D. Tenn.); *see also* CIA, available at https://oig.hhs.gov/fraud/cia/agreements/Ageless_Mens_Health_01222015.pdf. The Government respectfully submits that at least when he agreed to the CIA, if not when he became aware of the Government's investigation in that matter, Dr. Mitias should have been held to an even higher standard with regards to ensuring that he and his medical practices were engaging in proper coding and billing and in compliance with all applicable Federal health care program requirements.

Accordingly, the Government need not "present its best case or even a particularly *good* case" in its pleadings, but rather must only "state a plausible case." *Id.* at 263. Nevertheless, the Government has pled a wealth of allegations evincing that Mitias had requisite knowledge.

Mitias admitted to the relator that it used and billed for the non-approved VAs to maximize profit. Dkt. 37, ¶¶ 64-66, 71. To do so, Mitias had to have recklessly disregarded or deliberately ignored all guidance published by CMS. Effective January 1, 2010, CMS published Billing and Coding Guidelines that stated that "[t]here are 2 different products that are billed using this code [J7325]," Synvisc and Synvisc-One, seemingly leaving no confusion as to whether other VAs could be billed under that same code. Subsequently, effective April 12, 2012, the Mississippi MACs (first Highmark Medicare Services, then Novitas Solutions, Inc.) issued LCD L32237.[24] Dkt. 37, ¶ 78 fn.6. The LCD stated that it was addressing "[v]arious polymers hyaluronic acid [that] have been approved and marketed as implanted prosthetic devices." It said that "Medicare will cover the cost of the injection and the injected hyaluronate polymer for patients who meet the following clinical criteria: …The prosthetic device is approved by the Food and Drug Administration (FDA) for Intra-articular injection." Coverage guidance further required that, to be considered reasonable and necessary, it be "Safe and effective"; "Not experimental or investigational"; "Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition…"; and "Ordered and furnished

[24] While not binding authority, the draft LCD, which was posted for comment on September 20, 2011, was also adequate to at least put Mitias on notice that he needed to seek clarification of his proposed interpretation of the billing codes and regulations.

by qualified personnel."[25]

Defendants ignored all CMS and MAC guidance for *five years*, including for nearly a year after the relator warned them they were wrong. Dkt. 37, ¶¶ 59-72. This guidance, in addition to the plain language of the J-codes, alerted Mitias that Medicare would not cover, i.e., reimburse, for VA injections performed as alleged in the Complaint.[26]

Defendants argue they "held an honest belief" that they were permitted to bill non-approved compounds under the codes for brand-name VAs (Dkt. 43 at 8-9), but that is an affirmative defense more appropriately raised at summary judgment. *See U.S. ex rel. Streck v. Bristol-Myers Squibb Co.* 2018 U.S. Dist. LEXIS 202104, at *32-33 (E.D. Pa. Nov. 29, 2018) ("Because this inquiry turns on the determination of facts, a court should not resolve an FCA claim at the motion to dismiss stage where the plaintiff plausibly alleges that the defendant proceeded with its interpretation in the face of contrary guidance."); *c.f. Bollinger*, 775 F.3d at 263 (remanding where district court "prematurely" applied the government knowledge defense). Moreover, since 2010, there has been **no** guidance issued by Medicare even **suggesting** that a provider could bill a non-approved VA under *any* code, or that anything *except* the brand-name

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[25] Even if Defendants were correct that this LCD is not binding (this flawed argument is addressed in Section II(D), *supra*), it still evinces that Mitias was warned and failed to make necessary inquiries.

[26] *U.S. ex rel. Durkin v. Cty. of San Diego*, 2018 U.S. Dist. LEXIS 114744 (S.D. Cal. July 10, 2018)—a California opinion that held the relator failed to plead how a subordinate who signed the false certifications had scienter—is both inapposite and has been rejected by the Fifth Circuit. *See U.S. ex rel. Rigsby v. State Farm Fire & Cas. Co.*, 794 F.3d 457, 479 (5th Cir. 2015) ("State Farm's constricted theory of FCA liability would enable managers at an organization to concoct a fraudulent scheme—leaving it to their unsuspecting subordinates to carry it out on the ground—without fear of reprisal. The FCA is not so limited."). Moreover, here, Dr. Mitias is both the decisionmaker responsible for the submission of the False Claims and his scienter is individually pled. *See* Dkt. 37, ¶¶ 8, 65-71; *see also Stevens*, 605 F. Supp. 2d at 867 (provider responsible for own billing).

VAs could be billed under their respective J-codes.[27] Mitias was not permitted to bury its head in the sand and continue to bill under its own preposterous interpretation of Medicare codes and regulations.[28]

IV. CONCLUSION

The Government has pled that Mitias knowingly submitted false claims that were material to Medicare's payment decisions. Accordingly, the Court should deny its motion.[29]

Respectfully submitted this 25th day of March, 2020.

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[27] As discussed in footnote 14, *supra*, the May 30, 2012 letter unequivocally supports the Government's proposed interpretation. Regardless, even if Mitias "believed" the letter supported his interpretation, it has no relevance to his state of mind prior to receipt, in December 2014. Dkt. 43 at 9.

[28] Moreover, if and when Mitias did receive such clarification, so that it knew its previous interpretation was in error, it was obligated to self-report and repay Medicare for his ill-gotten gains. The Government thus reserves the right to amend its complaint to include a claim under 31 U.S.C. § 3729(a)(1)(G).

[29] If the Court finds that the Government has failed to adequately plead any of its claims, the Government requests leave to amend to correct any pleading deficiencies. *N. Cypress Med. Ctr. Operating Co., Ltd. v. Aetna Life Ins. Co.*, 898 F.3d 461, 478 (5th Cir. 2018) (leave to amend should be freely granted).

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CERTIFICATE OF SERVICE

I hereby certify that I have electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record on this the 25th day of March, 2020:

/s/ J. Harland Webster